REMARKS

The rejection of Claims 1 and 2 under 35 U.S.C. §102(b) over Hadley et al is respectfully traversed. Hadley et al describes topical application of estrogens, but the DHEA of the present invention is not an estrogen.

Hadley et al, at page 105 states that "*estrogens* administered topically to relieve menopausal symptoms can produce hyperpigmentation of the skin" (emphasis added). However, DHEA is not an estrogen. Rather, DHEA is an androsterone (dehydroepiandrosterone; present application at page 3, line 15.) Thus, Hadley et al fails to anticipate the methods and composition of the present invention.

Moreover, because estrogens and androsterones are known to have quite different physiological properties, there is no reasonable basis for expecting that estrogens and DHEA would have similar properties as components of topically applied compositions. Accordingly, Hadley et al also fails to suggest the claimed methods or composition. Applicants therefore respectfully request withdrawal of the rejection.

The rejection of Claims 1-35 under 35 U.S.C. §103(a) over Hadley et al in view of Breton is respectfully traversed. Hadley et al only describes the topical application of estrogens, not DHEA, and Breton fails to describe methods for regulating the pigmentation, depigmenting, or pro-pigmenting skin and/or superficial body growths, nor the claimed composition.

As discussed above, Hadley et al describes the topical administration of estrogens. At page 106 (Section 2), Hadley et al only teaches that manipulation of *systemic* levels of androgens affects melanin production. For example, Hadley et al discuss the effects of castrating rats or "administration of an androgen" on the pigmentation of rats, the effects of

"androgen excess" on human female pigmentation, and the effects of "testosterone implants" on male golden hamster pigmentation. However, Hadley et al fails to describe the *topical* administration of androgens to control pigmentation. Indeed, the Office also states that Hadley et al "lacks formulations of steroidal hormones as topical compositions."

Breton describes compositions containing sodium dehydroisoandrosterone 3-sulfate (S-DHEA), for the purpose of "treating wrinkles and fine lines, and for firming skin tissue" (col. 1, lines 61-62. Although Breton states that cutaneous aging may include, in part, "pigmentation marks" (col. 1, line 24), Breton fails to describe using compositions containing DHEA or its derivatives for the purpose of controlling such pigmentation marks. Rather, as discussed at column 1, lines 26-56, pigmentation marks are only one of many manifestations of cutaneous aging, and Breton only describes the topical application of S-DHEA compositions for a specific subset of these manifestations of cutaneous aging, treating wrinkles and fine lines and for firming skin tissue. Thus, Breton also fails to recognize that S-DHEA could be useful in compositions for regulating the pigmentation, depigmenting, or pro-pigmenting of skin and/or superficial body growths.

As discussed above, Hadley et al fails to describe the topical application of androgens, and Breton only describes methods of treating wrinkles and fine lines and for firming skin tissue. Thus, the combination of Hadley et al and Breton fails to describe a method for regulating the pigmentation, depigmenting, or pro-pigmenting of skin and/or superficial body growths, and fails to describe the claimed compositions containing DHEA and depigmenting agents. Accordingly, the combination of Hadley et al and Breton fails to suggest the claimed methods and composition.

The rejection of the claims under 35 U.S.C. §112, second paragraph is traversed in part, and obviated by appropriate amendment in part. In regard to Claims 4, 15, and 26, the phrase "(or a diol)" has been deleted. In regard to Claims 34-35, the phrase "in particular" has been deleted. In addition, Claim 34 now recites "arbutin and derivatives thereof."

In regard to the term "derivative," the present specification describes in detail the types of compounds which are metabolic derivatives of DHEA (at page 5, lines 18-20). Thus, the specification does, in fact, provide a standard for ascertaining which compounds are derivatives. Applicants therefore respectfully request withdrawal of the rejection.

In regard to the specification, the Examiner states that the "incorporation of essential material in the specification by reference" is improper. However, Applicants respectfully submit that benzotriazoles and benzotriazole silicones are well known compounds, and therefore the incorporation by reference of the documents at page 8, line 21 is not essential material. Likewise, depigmenting agents such as kojic acid, ellagic acid, arbutin, hydroquinone, etc. are well known, and therefore the documents incorporated by reference at page 9, lines 7-16 are not essential material. In addition, the compound of formula I is expressly disclosed at page 9, and is therefore not essential material. Finally, Applicants note that MPEP §608.01(p) permits the incorporation by reference of priority applications. Accordingly, the incorporation by reference of French Patent Application Serial No. 9912773 is proper. Applicants therefore respectfully request withdrawal of the objection to the specification.

Finally, Applicants note that EP 0853472 A1 corresponds to WO 97/12597, which was filed in an Information Disclosure Statement on October 12, 2000.

Accordingly, and for the reasons stated above, Applicants respectfully request withdrawal of the rejections.

Applicants submit that the present application is in condition for allowance. Early notification to this effect is respectfully requested.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.

Thomas A. Blinka

Stephen G. Baxter, Ph.D.
Registration No. 32,884

Thomas A. Blinka, Ph.D.
Registration No. 44,541

22850

(703) 413-3000
Fax #: (703) 413-2220
NFO/TAB/law

I:\atty\tab\196726-am.wpd

Marked-Up Copy
Serial No:09/686,997
Amendment Filed on:
October 30, 2001

IN THE CLAIMS

Please amend the claims as follows:

--4. (Amended) The method of Claim 1, wherein said metabolic derivative thereof is selected from the group consisting of 5-androstene-3β,17β-diol [(or a diol)], 5-androstene-3β,17β diol sulfate and 4-androstene-3,17-dione.

15. (Amended) The method of Claim 12, wherein said metabolic derivative thereof is selected from the group consisting of 5-androstene-3β,17β-diol [(or a diol)], 5-androstene-3β,17β-diol sulfate and 4-androstene-3,17-dione.

26. (Amended). The method of Claim 23, wherein said metabolic derivative thereof is selected from the group consisting of 5-androstene-3β,17β-diol [(or a diol)], 5 androstene-3β,17β-diol sulfate and 4-androstene-3,17-dione.

34. (Amended) A composition comprising, in a physiologically acceptable medium, DHEA or at least one biological precursor thereof or metabolic derivative thereof, and at least depigmenting agent selected from the group consisting of kojic acid, ellagic acid, arbutin and derivatives thereof, hydroquinone, aminophenol derivatives, iminophenol derivative, L-2-oxothiazolidone-4-carboxylic acid or procysteine and salts and esters thereof; and plant extracts, [in particular] extract of liquorice, extract of mulberry and extract of skullcap.

35. (Amended) The composition of Claim 34, wherein said at least one depigmenting agent is selected from the group consisting of N-cholesteryloxycarbonyl-para-aminophenol, N-ethyloxycarbonyl-para-aminophenol, 4-carboxylic acid or procysteine, as well as its salts and esters; and plant extracts, [in particular] extract of liquorice, extract of mulberry and extract of skullcap.--